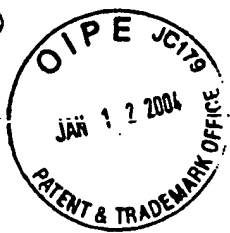


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Attorney's Docket No.: 11984-005001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Peter J. Shortridge et al. Art Unit : 3643
Serial No. : 09/641,114 Examiner : J. Gellner
Filed : August 17, 2000
Title : METHOD FOR MINIMIZING CONTAMINATION OF CROPS AND
PRODUCTS DERIVED THEREFROM

MAIL STOP APPEAL BRIEF - PATENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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The following documents relating to this application are enclosed.

1. Appeal Brief and Appendix A, in triplicate (25 pages);
2. Check in the amount of \$165 for Appeal Brief; and
4. Postcard.

Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: January 6, 2004

M. Angela Parsons
M. Angela Parsons, Ph.D.
Reg. No. 44,282

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696
60187537.doc

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BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is Northland Seed & Grain Corp.

(2) Related Appeals and Interferences

None.

(3) Status of Claims

Claims 1-35 and 43-61 are pending, and stand finally rejected.

(4) Status of Amendments

All amendments have been entered

(5) Summary of Invention

The claimed invention relates to activities carried out by farmers or grain handlers and processors, specifically, growing and processing non-genetically modified (non-

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GMO) grain or genetically modified (GMO) grain. The business of growing and processing non-GMO grain or GMO grain, and more importantly, verifiably keeping one from contaminating the other, has become important in today's agricultural economy. There is a large market, both foreign and domestic, for such grain. This market has arisen, in part, due to the controversy over genetically modified (GMO) grain. Given the prevalence of GMO crops in the U.S., however, there is significant concern among buyers of non-GMO grain that their purchases have GMO contamination. The present invention provides means for minimizing contamination of non-GMO grain by GMO grain, or similarly, contamination of GMO grain by non-GMO grain. [page 1, lines 7-24]

In one aspect, the claimed invention includes selecting a non-genetically modified seed stock for planting [page 9, lines 7-15]; certifying that the non-genetically modified seed stock was planted and grown under conditions effective for harvesting a crop containing 5% or less, 1% or less, 0.1% or less, or 0.01% or less genetically modified seeds [page 6, lines 2-9 and 19-25; page 7, line 14 - page 8, line 26; page 11, line 3 - page 12, line 19]; harvesting the crop [page 12, lines 19-20]; processing the crop under conditions effective for producing processed grain containing 5% or less, 1% or less, 0.1% or less, or 0.01% or less, respectively, genetically modified seeds [page 11, lines 3-17; page 14, lines 1-16; page 15, lines 4-31]; and certifying that the crop was processed under such processing conditions [page 6, lines 2-9; page 17, line 10 - page 18, line 28; page 21, lines 3-12].

The invention also, in general, relates to methods for preventing contamination of non-genetically modified processed grain when the potential for contamination by genetically modified seeds exists. Specifically, the method includes harvesting and certifying that a crop contains less than 5%, less than 1%, less than 0.1%, or less than 0.01% genetically modified seeds [page 6, lines 2-9 and 19-25; page 7, line 14 - page 8, line 26; page 11, line 3 - page 12, line 19]; processing the crop under conditions effective for producing processed grain containing less than 5%, less than 1%, less than 0.1%, or less than 0.01% genetically modified seeds [page 11, lines 3-17; page 14, lines 1-16; page 15, lines 4-31]; and certifying that the crop was processed under such processing

conditions [page 6, lines 2-9; page 17, line 10 – page 18, line 28; page 21, lines 3-12].

The invention also, in general, relates to methods of preparing GMO grain or a processed food product certified to contain 5%, 1%, 0.1%, 0.01%, or less contamination by non-GMO seeds or crop material. [page 18, line 29 – page 19, line 6; page 19, lines 13-17 and 25-29]

The certifying steps can include obtaining DNA test results or can include obtaining application susceptibility test results [page 9, line 16 – page 11, line 2; page 16, lines 1-13; page 19, line 29 – page 20, line 8]. The certifying steps can include inspecting the acreages that are to be planted [page 11, lines 18-26], the storage bins that are to hold the seed or grain [page 12, lines 3-15; page 13, lines 7-12; page 16, lines 24-26], or the processing plants [page 15, lines 4-31; page 16, line 26 – page 18, line 3; page 21, lines 3-12]. Other embodiments for practicing the claimed methods are disclosed.

(6) Issues

1) Whether claims 1-3, 6-10, 13-21, 22-25, 28, 29, 30-33, and 43-61 are obvious over a newspaper article, 1998 *Chicago Sports Final Edition* ('Reuters Advises Farmers to Separate Their Genetically Modified Crops'; hereafter "Reuters") in view of a plant breeding textbook, (*Breeding Field Crops*, 2nd Ed., 1979, AVI Publishing Co., Inc., pgs 449-58; hereafter "Poehlman");

2) Whether claims 4, 5, 26, and 27 are obvious over Reuters in view of Poehlman in further view of the Lander reference (*Use of DNA in Identification*, "Winding Your Way Through DNA" symposium, 1992, pg 6; hereafter "Lander"); and

3) Whether claims 11, 12, 34, and 35 are obvious over Reuters in view of Poehlman in view of the Montanari et al. reference (U.S. Patent No. 5,478,990; hereafter "Montanari").

(7) Grouping of Claims

Claims 1-7, 16, 19, and 52-55 do not stand or fall together because each claim recites a different percent contamination by genetically modified seeds in different steps

of the method. The claimed percentages are separately patentable, and the claimed percentages in the different steps of the method are separately patentable.

Claims 8-10, 13-15, 17-18, and 20-21 stand or fall with claim 1.

Claim 11 does not stand or fall with claim 1 as claim 11 recites a separately patentable embodiment of one of the method steps.

Claim 12 stands or falls with claim 11.

Claims 22-29 and 56-58 do not stand or fall together because each claim recites a different percent value of genetically modified seeds in different steps of the method. The claimed percentages are separately patentable, and the claimed percentages in the different steps of the method are separately patentable.

Claims 30-33 stand or fall with claim 22.

Claim 34 does not stand or fall with claim 22 as claim 34 recites a separately patentable embodiment of one of the method steps.

Claim 35 stands or falls with claim 34.

Claims 43-44 and 59-61 do not stand or fall together because each claim recites a different percent value of genetically modified seeds in different steps of the method. The claimed percentages are separately patentable, and the claimed percentages in the different steps of the method are separately patentable.

Claim 45 does not stand or fall with claim 43 as claim 45 recites a separately patentable embodiment of one of the method steps.

Claims 46-51 stand or fall with claim 43.

(8) Argument

The claim rejections and Applicants' arguments to the rejections are as follows. Copies of the cited court cases are included in Appendix A.

The 35 U.S.C. §103 Rejections Over Reuters and Poehlman

The Examiner rejected claims 1-3, 6-10, 13-21, 22-25, 28, 29, 30-33, and 43-61 under 35 U.S.C. §103(a) as being unpatentable over Reuters in view of Poehlman. Applicants respectfully traverse this rejection.

Independent Claims 1, 22, and 43

The Examiner stated in the Final Office Action mailed August 11, 2003 that Reuters discloses the motivation to certify for contamination by genetically modified crop material. The Examiner further asserted that Poehlman discloses the method steps of: preparing a non-genetically modified processed food product comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less genetically modified seed; and harvesting, processing, and certifying the crop. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as disclosed by Reuters to certify for contamination by genetically modified crop material so as to be able to sell their harvest.

Proper analysis under 35 U.S.C. §103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should carry out the claimed process, *and* (2) whether the prior art also would provide that in so carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 288, 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, there must be some teaching, suggestion, or incentive to make the claimed invention beyond the mere disclosure of individual components of the claimed invention either separately or in other combinations. *Northern Telecom, Inc. v Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990). A teaching, suggestion, or incentive to make the claimed combination must come from the prior art, and not the Applicant's invention itself. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). That is, the invention must be viewed not with the blueprint drawn by the inventor, but in view of the prior art. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985). The courts have emphasized that combining prior art references without evidence of a suggestion or motivation to do so "simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight...." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (citations omitted).

The Poehlman Reference

Poehlman is a textbook about plant breeding. Poehlman discloses the general process of breeding field crops to create new plant varieties and describes the process of generating breeder seed, foundation seed, and registered seed once a new variety has been bred. Such classes of seed typically are for use by other breeders, for further reproduction by foundation seed growers, or for sale to farmers, respectively. The seed stocks resulting from the new varieties produced by the methods disclosed in Poehlman can then be provided to growers (see page 449, column 2 and page 450, column 2). However, the seed stocks described in Poehlman are merely the starting point for the methods of the claimed invention.

Poehlman does not discuss problems encountered in preparing a non-genetically modified processed grain or food product and ensuring that such grain or food product is not contaminated by genetically modified seed or crop material. Similarly, Poehlman does not discuss problems encountered in preparing genetically modified processed grain and ensuring that such grain is not contaminated by non-genetically modified seeds. The production, processing, and marketing of a harvested crop are not the responsibility of a plant breeder. Therefore, Poehlman cannot disclose or suggest methods related to production, processing, and marketing of non-genetically modified processed grain certified to contain only low levels or no genetically modified grain. Similarly, Poehlman cannot disclose or suggest methods related to production, processing, and marketing of genetically modified processed grain certified to contain only low levels or no non-genetically modified seeds.

The Examiner considers Poehlman's visual screening procedures to be adequate to distinguish between genotypes when they cause different phenotypes. However, genetically modified plants generally cannot be distinguished from non-genetically modified plants by visual screening. A World Wide Web publication of the Illinois Agricultural Experiment Station states that "there is no easy way to distinguish GM soybeans from non-GM ones..." and "we can't distinguish visually any of the GM cross-pollinated kernels [of corn]...." StratSoy Soybean Answers, at http://web.aces.uiuc.edu/faq/faq.pdl?project_id=28&faq_id=590. A copy of Stratsoy

Soybean Answers was submitted in Applicants' IDS of January 16, 2001. See also, van Duijn et al. (1999, "Detection Methods for Genetically Modified Crops," *Food Control*, 10:375-8), which describes the detection limits for DNA- and protein-based methods to detect genetically modified plants. A copy of the van Duijn et al. reference can be found in Applicants' IDS submitted on January 12, 2001. Thus, the visual screening methods described in Poehlman are inadequate to distinguish non-genetically modified plants from genetically modified plants or vice versa, and are inadequate to determine the percentage of genetically modified or non-genetically modified seeds in a processed grain or food product, let alone a specific contamination percentage, e.g., 5% or less, 1% or less, 0.1% or less, or 0.01% or less.

In addition, genetically modified seeds or plants did not exist as of the 1979 publication date of Poehlman. As discussed in news articles from the *PR Newswire* (January 18, 1983) and *The Washington Post* (April 30, 1983), the first genetically modified plants were produced in 1983. Copies of the *PR Newswire* article and the *Washington Post* article can be found in Applicants' IDS submitted January 12, 2001. Thus, Poehlman discloses methods of producing certified planting seed and could not have envisioned methods of minimizing GMO contamination in non-GMO grain or, similarly, minimizing non-GMO contamination in GMO grain.

The Reuters Reference

Reuters is a short newspaper article covering an advisory to farmers and grain merchants. The advisory was issued by Arthur Daniel Midlands, a grain processing and handling company. This advisory was issued in 1998, shortly before crop harvest in the Midwest, and advised farmers and grain merchants to "segregate non-genetically enhanced crops to preserve their identity." Reuters briefly mentions physical separation of harvested crops, but does not suggest any particular method of doing so. Reuters does not mention or suggest keeping genetically modified crops free from contamination by non-genetically modified seeds.

The Reuters and Poehlman References

The combination of Poehlman and Reuters does not render the claimed methods patentably obvious. Poehlman contains no specific teaching or suggestion concerning certifying that a non-genetically modified processed grain or food product contains 5% or less genetically modified seeds or crop material or, similarly, that a genetically modified processed grain or food product contains 5% or less non-genetically modified seeds. Reuters merely mentions physical separation of harvested crops, and contains no specific suggestion concerning methods that would be applicable to identify genetically modified grain or non-genetically modified grain. Further, Poehlman and Reuters provide no reasonable expectation that farmers and grain merchants would have been successful in segregating genetically modified crops and non-genetically modified crops. In the absence of a reasonable expectation of success, the claimed methods are patentably non-obvious in view of the combination of Poehlman and Reuters.

Contrary to the Examiner's position, the seed certification process discussed in Poehlman is not applicable to the subject matter of the claimed invention. As indicated in the Declaration under 37 CFR §1.132 by Robert H. Peterson, submitted with Applicants' June 12, 2002 Response to Office Action, the discussion in Poehlman relates to state seed certification laws. Such laws apply to seed ultimately intended for sowing (*i.e.*, planting). Such laws do not apply to seeds of a harvested crop, because seeds of a harvested crop are not intended to be sown. Peterson Declaration, #17 and 18.

Although Poehlman discusses seed certification, it does not disclose farming or processing practices. There is no indication whatsoever in Poehlman that seed certification equates to farming and grain processing practices. Contrary to the Examiner's view, it is the opinion of Mr. Peterson, a person with extensive training and experience in plant breeding, that seed certification as described in Poehlman is not applicable to the methods recited in the pending claims. Peterson Declaration, #18 and 19. That is, the teachings of Poehlman do not apply to the problem of preventing contamination by genetically modified or non-genetically modified seed when growing, harvesting, and processing a non-genetically modified or genetically modified crop, respectively.

The differences between seed certification as discussed in Poehlman and conventional farming practices are recognized by Poehlman himself. For example, Poehlman states that small grains, rice, and soybean crops are planted by farmers "on large acreages." See page 456, left-hand column. Poehlman teaches that breeder seed involves merely "several hundred" plants or "several hundred" rows. See page 456, right-hand column. That is, the scale of operations involved in producing a crop is vastly larger than the scale of operations involved in producing the planting seed described in Poehlman.

In view of Mr. Peterson's Declaration and the remarks above, Applicants respectfully submit that Poehlman is non-analogous art. The Court in *In re Deminski* (796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986)) applied a two-step test to determine whether a prior art reference was non-analogous and thus not relevant in determining obviousness. According to the two-step test, it must be determined (1) whether the reference is "within the field of the inventor's endeavor," and (2) if not, whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved." Because Poehlman discloses seed certification practices that are not applicable to the activities of farmers or grain and food processors, Poehlman is not "within the field of the inventor's endeavor." Furthermore, because the scale of operations for production of certified seed as disclosed in Poehlman versus that for farming and processing grain as claimed herein is significantly different, Poehlman is not "reasonably pertinent to the particular problem with which the inventor was involved." Therefore, based on the two-step test, Poehlman is non-analogous art, and is therefore not relevant in determining obviousness of the instant claims.

The Examiner responded to Applicants' previous arguments by stating that the "Examiner considers Poehlman to disclose methods for keeping seed pure for both breeder and farmer seed."

Applicants disagree with the Examiner's statement. The seed certification practices disclosed in the Poehlman reference do not provide a reasonable expectation of success in achieving a low level of contamination when growing and processing a non-genetically modified or a genetically modified grain crop, based on the statements in the

Poehlman reference that are discussed above. Instead of relying on the teachings of the references, the Examiner has used hindsight in an attempt to make a *prima facie* case of obviousness. It is impermissible to use the inventor's application as a blueprint to reconstruct the invention from disparate disclosures in the prior art. "The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness" (*In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992)).

The emergence of genetically modified field crops has created new challenges, and methods to certify the absence of contamination by non-genetically modified seed has not been done or proposed before. Similarly, methods to certify the absence of contamination of non-genetically modified field crops by genetically modified seeds has not been done or proposed before. The claimed methods are not taught or suggested by the cited art. Rather, they are found only in the Applicants' disclosure. Applicants respectfully request that the rejection of independent claims 1, 22 and 43 under 35 USC §103 be reversed.

Dependent Claims 2-3, 6-7, 16, 19, 23-25, 28-29, 44-45, and 52-61

Claims 2-3, 6-7, 16, and 19 depend directly or indirectly from independent claim 1. Claims 23-25 and 28-29 depend directly or indirectly from independent claim 22. Claims 44-45 and 52-61 depend directly or indirectly from independent claim 43. Independent claims 1, 22, and 43 recite a contamination percentage of 5% or less.

Dependent claims 2-3, 6-7, 16, 19, 23-25, 28-29, 44-45, and 52-61 do not stand or fall with their respective independent claims or with each other because a method reciting a level of contamination of 5% or less in a harvested crop (steps a of claims 1 or 22) or processed grain or food product (steps b of claims 1 or 22; step c of claim 43) is patentably distinct from a method reciting a level of contamination of 1% or less in a harvested crop (claims 52 and 56) or processed grain or food product (claims 53, 57, and 59), which are patentably distinct from a method reciting a level of contamination of 0.1% or less in a harvested crop (claims 16, 23, and 54) or processed grain or food product (claims 16, 55, 58, and 60), which are patentably distinct from a method reciting

a level of contamination of 0.01% or less in a harvested crop (claims 2, 6, 19, 24, and 28) or processed grain or food product (claims 3, 7, 19, 25, 29, 44, and 61). For example, a conclusion that a claim reciting contamination of 5% or less in a harvested crop is patentably obvious in view of the cited art does not make a claim reciting contamination of 1% or less in processed grain patentably obvious.

With respect to claim 2, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a crop is planted, grown, and harvested can be certified such that the resulting harvested crop contains 0.01% or less contamination by GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested crop could have been certified to have GMO contamination of 0.01% or less.

With respect to claim 3, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested crop can be processed under conditions effective for producing a processed food product containing 0.01% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 0.01% or less.

With respect to claim 6, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a crop is planted, grown, and harvested can be certified, using application susceptibility tests, to contain 0.01% or less contamination by GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested crop could have been certified to have GMO contamination of 0.01% or less based on application susceptibility tests.

With respect to claim 7, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested crop can be certified, using application susceptibility tests, to have been processed under conditions effective for producing a processed food product containing 0.01% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one

of skill that a processed food product could have been certified to have GMO contamination of 0.01% or less based on application susceptibility tests.

With respect to claim 16, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a crop is grown, harvested, and processed can be certified such that the resulting processed food product contains 0.1% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 0.1% or less.

With respect to claim 19, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a crop is grown, harvested, and processed can be certified such that the resulting processed food product contains 0.01% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 0.01% or less.

With respect to claim 23, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested GMO crop can be certified to contain 0.1% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested GMO crop could have been certified to have contamination by non-GMO seeds of 0.1% or less.

With respect to claim 24, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a GMO crop is planted and grown can be certified such that the resulting harvested crop contains 0.01% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested GMO crop could have been certified to have contamination by non-GMO seeds of 0.01% or less.

With respect to claim 25, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested GMO crop can be certified to have been processed under conditions effective for producing processed grain containing 0.01% or less contamination by non-GMO seeds. Therefore, the combined references provide no

reasonable expectation of success to one of skill that a processed grain could have been certified to have contamination by non-GMO seeds of 0.01% or less.

With respect to claim 28, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a GMO crop is planted, grown, and harvested can be certified, using application susceptibility tests, to contain 0.01% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a GMO harvested crop could have been certified to have contamination by non-GMO seeds of 0.01% or less based on application susceptibility tests.

With respect to claim 29, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested GMO crop can be certified, using application susceptibility tests, to have been processed under conditions effective for producing processed grain containing 0.01% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that processed grain could have been certified to have contamination by non-GMO seeds of 0.01% or less based on application susceptibility tests.

With respect to claim 44, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested crop can be tested and certified to ensure that a processed food product produced from the crop contains 0.01% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested crop could have been certified to have contamination by GMO crop material of 0.01% or less.

With respect to claim 45, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a lot identification number can be established for a harvested crop such that processing of the crop can be certified so that the resulting processed food product contains 5% or less GMO contamination. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 5% or less using tracking lot identification numbers.

With respect to claim 52, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a crop is planted and grown can be certified such that the resulting harvested crop contains 1% or less contamination by GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested crop could have been certified to have GMO contamination of 1% or less.

With respect to claim 53, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a crop can be processed under conditions effective for producing a processed food product containing 1% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 1% or less.

With respect to claim 54, neither Poehlman nor Reuters, alone or combined, have any specific teaching that the conditions under which a crop is planted and grown can be certified such that the resulting harvested crop contains 0.1% or less contamination by GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested crop could have been certified to have GMO contamination of 0.1% or less.

With respect to claim 55, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested crop can be processed under conditions effective for producing a processed food product containing 0.1% or less contamination by GMO crop material. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 0.1% or less.

With respect to claim 56, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested GMO crop can be certified to contain 1% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that a harvested crop could have been certified to have contamination by non-GMO seeds of 1% or less.

With respect to claim 57, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested GMO crop can be certified to have been processed under conditions effective for producing processed grain containing 1% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that processed grain could have been certified to have contamination by non-GMO seeds of 1% or less.

With respect to claim 58, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a harvested GMO crop can be certified to have been processed under conditions effective for producing processed grain containing 0.1% or less contamination by non-GMO seeds. Therefore, the combined references provide no reasonable expectation of success to one of skill that processed grain could have been certified to have contamination by non-GMO seeds of 0.1% or less.

With respect to claim 59, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a processed food product can be certified to contain 1% or less GMO contamination. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 1% or less.

With respect to claim 60, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a processed food product can be certified to contain 0.1% or less GMO contamination. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 0.1% or less.

With respect to claim 61, neither Poehlman nor Reuters, alone or combined, have any specific teaching that a processed food product can be certified to contain 0.01% or less GMO contamination. Therefore, the combined references provide no reasonable expectation of success to one of skill that a processed food product could have been certified to have GMO contamination of 0.01% or less.

Accordingly, Applicants respectfully request that the rejection of claims 2-3, 6-7, 16, 19, 23-25, 28-29, 44-45, and 52-61 under 35 USC §103 be reversed.

Dependent Claims 8-10, 13-15, 17-18, 20-21, 30-33, and 46-51

Claims 8-10, 13-15, 17-18, 20-21 stand or fall with claim 1. Claims 30-33 stand or fall with claim 22. Claims 46-51 stand or fall with claim 43. Therefore, remarks concerning the non-obviousness of claims 8-10, 13-15, 17-18, 20-21, 30-33, and 46-51 can be found above with respect to the non-obviousness of claims 1, 22, and 43.

Conclusion

In view of the above remarks, Applicants respectfully request that the rejection of claims 1-3, 6-10, 13-25, 28-33, and 43-61 under 35 U.S.C. §103(a) as being unpatentable over Reuters in view of Poehlman be reversed.

The 35 U.S.C. §103 Rejection Over Reuters, Poehlman, and Lander

The Examiner rejected claims 4, 5, 26, and 27 under 35 USC §103(a) as being unpatentable over Reuters and Poehlman in further view of Lander. Applicants respectfully traverse this rejection.

Claims 4 and 5 depend from independent claim 1. Claims 26 and 27 depend from independent claim 22. Both independent claims recite a contamination percentage of 5% or less.

Dependent claims 4, 5, 26, and 27 do not stand or fall with their respective independent claims or with each other because a method reciting a level of contamination of 5% or less in a harvested crop (steps a of claims 1 and 22) or processed grain or food product (steps b of claims 1 and 22) is patentably distinct from a method reciting a level of contamination of 0.01% or less based on genetic tests in a harvested crop (claims 4 and 26) or processed grain or food product (claims 5 and 27). In other words, a conclusion that a claim reciting contamination of 5% or less in a harvested crop is patentably obvious in view of the cited art does not make a claim reciting contamination of 0.01% or less in processed grain based on genetic tests patentably obvious.

With respect to claim 4, the combined references provide no reasonable expectation of success to one of skill in the art that the conditions under which a crop is planted, grown, and harvested can be certified, using genetic tests to contain 0.01% or

less GMO crop material. None of the cited references, alone or combined, provide any teaching about the ability to certify 0.01% or less GMO contamination based on genetic tests.

With respect to claim 5, the combined references provide no reasonable expectation of success to one of skill in the art that the conditions under which a crop is processed can be certified, using genetic tests, such that the resulting processed food product contains 0.01% or less GMO crop material. None of the cited references, alone or combined, provide any teaching about the ability to certify 0.01% or less GMO contamination based on genetic tests.

With respect to claim 26, the combined references provide no reasonable expectation of success to one of skill in the art that a harvested GMO crop can be certified, using genetic tests, to contain 0.01% or less non-GMO seeds. None of the cited references, alone or combined, provide any teaching about the ability to certify 0.01% or less non-GMO contamination based on genetic tests.

With respect to claim 27, the combined references provide no reasonable expectation of success to one of skill in the art that processed GMO grain can be certified, using genetic tests, to contain 0.01% or less non-GMO seeds. None of the cited references, alone or combined, provide any teaching about the ability to certify 0.01% or less non-GMO contamination based on genetic tests.

The Lander reference discusses a DNA-based assay ("DNA fingerprinting") that compares loci from two different individuals to determine whether or not one individual is identical to the other individual. Lander makes only a brief mention of determining the similarities and differences among plants and makes no mention whatsoever of testing a sample of seeds for contamination (*i.e.*, "keeping seed pure"). Since no specific motivation to combine is found in the Lander reference, improper hindsight has been used to combine Lander with the other cited references.

The Examiner also asserted that detecting 1% or 0.01% contamination can be achieved by increasing the size of the sample. It is true that increasing sample size may decrease sampling error. However, "DNA fingerprinting" deals with the genotype as a whole, looking for similarities and differences between individuals at hundreds or

thousands of different genes. In other words, the overall genetic similarity and differences among individuals in a population is of interest to Lander. In contrast, the present invention deals with the presence or absence of particular transgenes. Lander contains no specific suggestion whatsoever to use DNA-based technology to assay a grain sample for the presence or absence of particular transgenes, and no transgene loci are tested by Lander. Rather, the use of Lander illustrates that isolated disclosures in the prior art have been combined to deprecate the claimed invention.

In view of the above, claims 4, 5, 26, and 27 are patentably nonobvious over the cited art, and Applicants respectfully request that the rejection under 35 USC §103 be reversed.

The 35 U.S.C. §103 Rejections Over Reuters, Poehlman, and Montanari

The Examiner rejected claims 11, 12, 34, and 35 under 35 USC §103(a) as being unpatentable over Reuters in view of Poehlman in view of Montanari. Applicants respectfully traverse this rejection.

Claims 11 and 12 depend directly or indirectly from independent claim 1. Claims 34 and 35 depend directly or indirectly from independent claim 22. Both independent claims recite a contamination percentage of 5% or less.

Dependent claims 12 and 35 stand or fall with claims 11 and 34, respectively. Dependent claims 11 and 34 do not stand or fall with their respective independent claims or with each other because a method reciting a level of contamination of 5% or less in a harvested crop (steps a of claims 1 and 22) or processed grain or food product (steps b of claims 1 and 22) is patentably distinct from the same method that further recites that the certifying step utilizes a lot identification number during processing of the grain (claims 11 and 34) or harvesting the crop (claims 12 and 35). For example, a conclusion that independent claim 1 or independent claim 22 is patentably obvious in view of the cited art does not make patentably obvious a dependent claim reciting that the certifying step uses a lot identification number during processing.

With respect to claim 11, the combined references provide no reasonable expectation of success to one of skill in the art that a crop can be certified to have been

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harvested and processed under conditions that result in the presence of 5% or less GMO crop material in the processed food product by establishing a lot identification number prior to the crop being processed and tracking the lot number during the processing steps. None of the cited references, alone or combined, provide any teaching about the ability to certify 5% or less GMO contamination using tracking lot identification numbers.

With respect to claim 34, the combined references provide no reasonable expectation of success to one of skill in the art that a crop can be certified to have been harvested and processed under conditions that result in the presence of 5% or less non-GMO seeds in the processed grain by establishing a lot identification number at the time the crop is harvested and tracking the lot number during the processing steps. None of the cited references, alone or combined, provide any teaching about the ability to certify 5% or less non-GMO contamination using tracking lot identification numbers.

Applicants submit that Montanari is non-analogous art. Montanari discloses animal processing practices. There would have been absolutely no motivation by one of ordinary skill in the art to look to the animal sciences art and the literature therein. When references in such disparate art areas are combined, it is clear that hindsight is being used. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Claims 12 and 35 stand or fall with claims 11 and 34, respectively. Therefore, remarks concerning the non-obviousness of claims 12 and 35 can be found above with respect to the non-obviousness of claims 11 and 34.

In view of the above remarks, the combination of Reuters and Poehlman further in view of Montanari does not make the claimed invention obvious. Thus, claims 11, 12, 34, and 35 are patentably non-obviousness under 35 USC §103, and Applicants request that the rejection be reversed.

The brief fee of \$165 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

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Date: January 6, 2004

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

60181890.doc

Respectfully submitted,

M. Angela Parsons
M. Angela Parsons, Ph.D.
Reg. No. 44,282

Appendix of Claims

1. A method for preparing a non-genetically modified processed food product, comprising:
 - a) certifying that a crop was grown and harvested under conditions effective for said crop to contain 5% or less genetically modified seeds; and
 - b) certifying that said crop was processed under conditions effective for said processed food product to contain 5% or less genetically modified crop material.
2. The method of claim 1, wherein said conditions in said certifying step a) are effective for said crop to contain 0.01% or less genetically modified seeds.
3. The method of claim 1, wherein said conditions in said certifying step b) are effective for said processed food product to contain 0.01% or less genetically modified crop material.
4. The method of claim 1, wherein said certifying step a) comprises obtaining genetic test results indicating that said non-genetically modified seeds contain 0.01% or less genetically modified seeds.
5. The method of claim 1, wherein said certifying step b) comprises obtaining genetic test results indicating that said processed food product contains 0.01% or less genetically modified crop material.
6. The method of claim 1, wherein said certifying step a) comprises obtaining application susceptibility test results indicating that said non-genetically modified seeds contain 0.01% or less genetically modified seeds.
7. The method of claim 1, wherein said certifying step b) comprises obtaining application susceptibility test results indicating that said processed food product contains 0.01% or less genetically modified crop material.
8. The method of claim 1, wherein said certifying step a) comprises testing said non-genetically modified seeds for contamination by genetically modified seeds prior to planting.
9. The method of claim 8, wherein said certifying step a) further comprises inspecting for contamination by genetically modified plants prior to harvesting said crop.
10. The method of claim 1, wherein said certifying step b) comprises:

i) inspecting for contamination by genetically modified seeds, prior to harvesting said crop, one or more storage bins for said crop; and

ii) inspecting for contamination by genetically modified seeds, prior to producing said processed food product, one or more processing plants that are to process said crop.--

11. The method of claim 1, wherein said certifying step b) comprises establishing a lot identification number for said crop prior to producing said processed food product and tracking said lot identification number during said processing.

12. The method of claim 11, wherein said lot identification number is established when said crop is harvested.

13. The method of claim 1, wherein said non-genetically modified seeds are seeds of a large-seeded grain crop.

14. The method of claim 13, wherein said non-genetically modified seeds are corn seeds.

15. The method of claim 14, wherein said processed food product is selected from the group consisting of corn sweetener, corn gluten meal, corn starch, corn meal and corn flour.

16. The method of claim 15, wherein said conditions in said certifying step a) and said conditions in said certifying step b) are effective for said processed food product to contain 0.1% or less genetically modified crop material.

17. The method of claim 13, wherein said non-genetically modified seeds are soybean seeds.

18. The method of claim 17, wherein said processed food product is selected from the group consisting of soy lecithin, soy flour, soy sauce, soy milk, soy desserts, textured soy protein, tofu and soy meal.

19. The method of claim 18, wherein said conditions in said certifying step a) and said conditions in said certifying step b) are effective for said processed food product to contain 0.01% or less genetically modified crop material.

20. The method of claim 1, wherein said non-genetically modified seeds are seeds of a small grain crop.

21. The method of claim 20, wherein said non-genetically modified seeds are rice seeds.

22. A method for minimizing contamination of genetically modified processed grain, comprising:

a) certifying that a harvested genetically modified crop contains less than 5% non-genetically modified seeds; and

b) certifying that said crop was processed under conditions effective for said genetically modified processed grain to contain less than 5% non-genetically modified seeds.

23. The method of claim 22, wherein said crop is certified at step a) to contain 0.1% or less non-genetically modified seeds.

24. The method of claim 23, wherein said crop is certified at step a) to contain 0.01% or less non-genetically modified seeds.

25. The method of claim 22, wherein said conditions in said certifying step b) are effective for said processed grain to contain 0.01% or less non-genetically modified seeds.

26. The method of claim 22, wherein said certifying step a) comprises obtaining genetic test results indicating that said genetically modified seeds contain 0.01% or less non-genetically modified seeds.

27. The method of claim 22, wherein said certifying step b) comprises obtaining genetic test results indicating that said processed grain contains 0.01% or less non-genetically modified seeds.

28. The method of claim 22, wherein said certifying step a) comprises obtaining application susceptibility test results indicating that said non-genetically modified seeds contain 0.01% or less non-genetically modified seeds.

29. The method of claim 22, wherein said certifying step b) comprises obtaining application susceptibility test results indicating that said processed grain contains 0.01% or less non-genetically modified seeds.

30. The method of claim 22, wherein said certifying step a) comprises testing genetically modified seeds to be used for growing said crop for contamination by non-genetically modified seeds prior to planting said genetically modified seeds.

31. The method of claim 30, wherein said certifying step a) further comprises inspecting said crop for contamination by non-genetically modified plants prior to harvesting said crop.

32. The method of claim 31, wherein said certifying step a) further comprises verifying that equipment used to grow and harvest said crop was cleaned-down prior to harvest.

33. The method of claim 22, wherein said certifying step b) comprises

i) inspecting for contamination by non-genetically modified seeds, prior to harvesting said crop, one or more storage bins that are to store said crop; and

ii) inspecting for contamination by non-genetically modified seeds, prior to processing said crop, one or more processing plants that are to process said crop.

34. The method of claim 22, wherein said certifying step b) comprises establishing a lot identification number for said crop prior to said processing.

35. The method of claim 34, wherein said lot identification number is established when said crop is harvested.

43. A method for minimizing contamination of a non-genetically modified processed food product, comprising:

a) inspecting a processing facility that is to process a harvested crop for contamination by genetically modified crop material, wherein said inspecting is performed prior to processing said harvested crop;

b) testing said harvested crop for contamination by genetically modified crop material, wherein said testing is performed prior to processing of said harvested crop by said processing facility to make said non-genetically modified processed food product; and

c) certifying that said processed food product contains 5% or less genetically modified crop material, based on said inspecting and testing.

44. The method of claim 43, wherein said testing step comprises obtaining genetic test results indicating that said processed food product contains 0.01% or less genetically modified crop material.

45. The method of claim 43, wherein said certifying step further comprises establishing a lot identification number for said crop prior to said testing step.

46. The method of claim 43, further comprising testing a plurality of samples obtained during processing of said crop.

47. The method of claim 43, wherein said harvested crop is a large seeded grain crop.

48. The method of claim 47, wherein said harvested crop is soybean

49. The method of claim 48, wherein said processed food product is selected from the group consisting of soy lecithin, soy sauce, soy meal, soy flour and soy milk.

50. The method of claim 43, wherein said harvested crop is a small grain crop.

51. The method of claim 50, wherein said harvested crop is wheat.

52. The method of claim 1, wherein said conditions in said certifying step a) are effective for said crop to contain 1% or less genetically modified seeds.

53. The method of claim 1, wherein said conditions in said certifying step b) are effective for said processed food product to contain 1% or less genetically modified crop material.

54. The method of claim 1, wherein said conditions in said certifying step a) are effective for said crop to contain 0.1% or less genetically modified seeds.

55. The method of claim 1, wherein said conditions in said certifying step b) are effective for said processed food product to contain 0.1% or less genetically modified crop material.

56. The method of claim 22, wherein said crop is certified at step a) to contain 1% or less non-genetically modified seeds.

57. The method of claim 22, wherein said conditions in said certifying step b) are effective for said processed grain to contain 1% or less non-genetically modified seeds.

58. The method of claim 22, wherein said conditions in said certifying step b) are effective for said processed grain to contain 0.1% or less non-genetically modified seeds.

59. The method of claim 43, wherein said processed food product is certified at step c) to contain 1% or less genetically modified crop material, based on said inspecting and testing.

60. The method of claim 43, wherein said processed food product is certified at step c) to contain 0.1% or less genetically modified crop material, based on said inspecting and testing.

61. The method of claim 43, wherein said processed food product is certified at step c) to contain 0.01% or less genetically modified crop material, based on said inspecting and testing.